



1631

Docket No. 20488/25-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Pospisilik et al.

ART UNIT: 1631

SERIAL NO.: 09/932,546

CONFIRMATION NO.: 4799

FILED: August 17, 2001

FOR: **USE OF DIPEPTIDYL PEPTIDASE IV EFFECTORS FOR  
LOWERING BLOOD PRESSURE IN MAMMALS**

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CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By:

*Sandra J. Wittrup*  
Sandra J. Wittrup

Date

*November 20, 2003*

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Date: November 20, 2003

Pursuant to Applicant(s) duty of disclosure, the information listed in the attached form PTO-1449 is brought to the attention of the Examiner. Copies of the listed items are enclosed.

The citation of the listed items is not a representation that they constitute a complete or exhaustive listing of the relevant art or that the references are prior art. The items listed are submitted in good faith, but are not intended to substitute for the Examiner's search. It is hoped, however, that in addition to apprising the Examiner of these particular items, they will assist in identifying fields of search and in making as full and complete a search as possible.

The filing of this information disclosure statement is not an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

In accordance with the requirement under 37 C.F.R. 1.98 (3)(i), the following are concise explanations of the relevance, as presently understood, with regard to those items submitted herewith that are not in the English language:

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

- a. ☒ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

- a. ☐ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

FEES

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)  
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1)). No fee or certification is required.
- b. ☐ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or certification is required.
- c. ☒ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office

Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):  
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

- a. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).  
or  
b. ☐ See the certification below. No fee is required.

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby certifies that

- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.
- c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office as indicated in the Form 1449 by those references having an asterisk(\*). As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

- ☐ A check in the amount of \$180.00 is enclosed for the above-indicated fee. A duplicate copy of this paper is attached.
- ☒ No fee is required.

VII. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.704(d) (PATENT TERM ADJUSTMENT)


Applies to original applications (other than design) filed on or after May 29, 2000.

- a. \_\_\_\_\_ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- b.   X   Enclosed herewith is form PTO-1449.
- c.   X   Copies of cited references are enclosed.
- d. \_\_\_\_\_ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

If the Examiner has any questions concerning this IDS, the Examiner is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition, if necessary) and charge any additional fees to Deposit Account No. 50-0369.

Respectfully submitted,

Date: November 20, 2003

  
\_\_\_\_\_  
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 20488/25-CIP		SERIAL NO. 09/932,546	
				APPLICANT(S): Pospisilik et al. et al.			
				FILING DATE: August 17, 2001		ART UNIT: 1631	
UNITED STATES PATENT DOCUMENTS							
EXAM. INITIAL		DOCUMENT NUMBER	DATE	INVENTOR	CLASS	SUB CLASS	FIL. DATE IF APPR
	AA	6,011,155	01/04/2000	Villhauer	544	333	
	AB	6,107,317	08/22/2000	Villhauer	514	365	
	AC	6,110,949	08/29/2000	Villhauer	514	365	
	AD	6,124,305	09/26/2000	Villhauer	514	272	
	AE	6,172,081	01/09/2001	Damon	514	307	
	AF	5,705,483	01/06/1998	Galloway et al.	514	12	
	AG	2001/0025023 A1	09/27/2001	Carr	514	2	
	AH	6,548,481 B1	04/15/2003	Demuth et al.	514	19	11/28/00
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)							
	CA	Wen-Tien Chen et al. "Seprase Complexes in Cellular Invasiveness", <i>Cancer and Metastasis Reviews</i> 22: 259-269, (2003).					
	CB	Victor A. Gault et al., "Glucose-Dependent Insulinotropic Polypeptide Analogues and Their Therapeutic Potential for the Treatment of Obesity-Diabetes", <i>Biochemical and Biophysical Research Communications</i> 308: 207-213, (2003).					
	CC	Lader, Malcolm H., MD, "Assessment Methods and the Different Diagnosis of Anxiety", <i>Journal of Clinical Psychopharmacology</i> , (1981), Vol. 1, No. 6, pp. 342-349.					
	CD	Winslow, R., "Novartis Drug Alters Picture for Diabetes" <i>Wall Street Journal</i> , Wed., December 27, 2000, p. B2.					
	CE	Ansorge, S., et al., "Membrane-bound peptidases of lymphocytes: Functional implications", <i>Biomed. Biochim. Acta</i> 50 (1991) 4-6, pp. 799-807.					
	CF	Dodge, R.W., et al., "Folding and Unfolding Kinetics of the Proline-to-Alanine Mutants of Bovine Pancreatic Ribonuclease A," <i>Biochemistry</i> 1996, 35, pp. 1548-1559.					
	CG	Demuth, Hans-Ulrich, "Recent Developments in Inhibiting Cysteine and Serine Proteases", <i>J. Enzyme Inhibition</i> , 1990, Vol. 3, pp. 249-278.					
	CH	Gomez, S., et al., "Relationship between endo- and exopeptidases in a processing enzyme system: Activation of an endoprotease by the aminopeptidase B-like activity in somatostatin-28 convertase", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 85 pp. 5468-5472, August 1988.					
	CI	Hegen, M., et al., "The T Cell Triggering Molecule Tp103 is Associated with Dipeptidyl Aminopeptidase IV Activity," <i>The Journal of Immunology</i> , vol. 144, pp. 2908-2914, No. 8, April 15, 1990.					
Examiner:					Date:		



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		FILING DATE: August 17, 2001	ART UNIT: 1631
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)			
CJ	Ishiura, S., et al., "Identification of a putative amyloid A4-generating enzyme as a prolyl endopeptidase," <i>Federation of European Biochemical Societies</i> , Vol. 260, No. 1, pp. 131-134, January 1990.		
CK	Kräusslich, Hans-Georg, et al., "Viral Proteinases", <i>Ann. Rev. Biochem.</i> 1988, 57 pp. 701-754.		
CL	Pederson, R.A., et al., "Improved Glucose Tolerance in Zucker Fatty Rats by Oral Administration of the Dipeptidyl Peptidase IV Inhibitor Isoleucine Thiazolidide", <i>Diabetes</i> , Vol. 47, August 1998 pp. 1253-1258.		
CM	Vanhoof, G., et al., "Proline motifs in peptides and their biological processing", <i>The FASEB Journal</i> , Vol. 9, June 1995, pp. 736-744.		
CN	Walter, R., et al., "Proline Specific Endo- and Exopeptidases", <i>Molecular &amp; Cellular Biochemistry</i> , Vol. 30, No. 2, April 18, 1980, pp. 111-127		
CO	Kessler, Von Horst, "Konformation und biologische Wirkung von cyclischen Peptiden", <i>Angew. Chem.</i> 94 (1982) pp. 509-520.		
CP	Kirschke, H. et al., "Proteinases 1: Lysosomal Cysteine Proteinases" <i>Protein Profile</i> , Vol. 2, Issue 14, 1995, pp. 1583-1634.		
CQ	Yaron, A., et al., "Proline-Dependent Structural and Biological Properties of Peptides and Proteins" <i>Critical Reviews in Biochemistry and Molecular Biology</i> , 28(1), pp. 31-81 (1993).		
CR	Vallee et al., "Larval Development of Tribolium Confusum in the Presence of Non-Naturally Occurring Amino Acids", Database CAPLUS on STN, Accession No.: 1963:75103, <i>Annales de l'ACFAS</i> (1962), 28, p. 26-27 (abstract).		
CS	Holst, J. et al., "Inhibition of the Activity of Dipeptidyl-Peptidase IV as a Treatment for Type 2 Diabetes", <i>Diabetes</i> , 47, 11, Health & Medical Complete pp. 1663-1670, Nov. 1998.		
CT	Augustyns et al., "Pyrrolidides: Synthesis and Structure-Activity Relationship as Inhibitors of Dipeptidyl Peptidase IV", <i>Eur. J. Med. Chem</i> (1997), vol. 32, pages 301-309.		
Examiner:		Date:	